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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/117,838

08/12/1998

OLEG LLIICH EPHSTEIN

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10/08/2008

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EXAMINER

PESELEV, ELLI

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

10/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Claims 45-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 is indefinite in that it depends from the cancelled claim 35.

Method claims 46-48 are indefinite in that the disease or condition being treated has not been set forth.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 19-21, 23, 25-27 and 45-48 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jonsson et al (U.S. Patent No. 4,292,324).

Jonsson et al disclose a method of making a pharmaceutical composition by combining one or more active substances and a method of treatment with said composition. Since the active substance and a homeopathic substance are chemically homogeneous, said substances encompass a compound having the

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same chemical structure and combining said substances into a single composition would inherently result in the prior art's composition

Claims 29 and 38 are rejected under 35 U.S.C. 102((b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cohen et al (U.S. Patent No. 3,901,967).

Cohen et al disclose a pharmaceutical comprising atropine sulfate. The claimed composition comprising atropine sulfate and a homeopathic dilution of atropine sulfate is inherent in the prior art's composition.

Claims 30 and 39 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sirany (U.S. Patent No. 4,987,127).

Sirany discloses a pharmaceutically composition comprising acetylsalicylic acid. The claimed composition comprising acetylsalicylic acid and a homeopathic dilution of acetylsalicylic acid is inherent in the prior art' composition.

Claims 31, 40 and 41 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nobile (U.S. Patent No. 3,134,718).

Nobile discloses a pharmaceutical composition comprising Prednizolon. The claimed medication comprising prednizolone and a homeopathic dilution of Prenizolone is inherent in the prior art's composition.

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Claims 32 and 42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Massey (U.S. Patent No. 4,839,341).

Massey disclose a pharmaceutical composition of insulin. The claimed composition comprising insulin and a homeopathic dilution of insulin is inherent in the prior art's composition.

Claims 33 and 43 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jonsson et al (U.S. Patent No. 4,292,342).

Jonsson et al disclose a pharmaceutical composition comprising zinc. The claimed composition comprising zinc and a homeopathic dilution of zinc is inherent in the prior art's composition.

Claims 43 and 44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Albert Stock John et al (U.S. Patent No. 3,032,584).

Albert Stock John et al disclose a pharmaceutical composition comprising Sarcolysin. The claimed composition comprising Sarcolysin and a homeopathic dilution of Sarcolysin, is inherent in the prior art's composition.

Applicant's arguments filed August 1, 2008 and September 10, 2008 have been fully considered but they are not persuasive.

Applicant contends that a therapeutic medicine and a homeopathic dilution of said medicine are not the same. This argument has not been found persuasive since applicant has not pointed out how the structural formula of a

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therapeutic medicine differs from the structural formula of a homeopathic dilution of said medicine. The claimed composition encompass nothing more than combining the same medicine in different concentration resulting in medicine which is patentably indistinguishable from the conventional medicine disclosed in the prior art of record.

Applicant further contends that the prior art of record does not disclose a therapeutically active compound that "possess enhanced therapeutic properties in comparison with said active medicine alone". This argument has not been found persuasive since applicant has not presented data comparing the claimed composition with the prior art's composition which is commensurate in scope with the claimed invention.

The declaration of Dr. Epstein filed 2/8/2008 has been considered.

The declaration does not present data relating to atropine sulfate, acetylsalicylic acid, insulin, zinc and sarcosine encompassed by the present claims.

With respect to prednisolone, the declaration states that the combined administration of ultra low dose of prednisolone and prednisolone resulted in reduction of side effects. However, it is not clear from said statement the number of subjects treated and it is not clear from said statement the dosage of prednisolone itself administered. Therefore, the significance of the results presented cannot be ascertained.

It is still unclear how an ultra low dose of a medicine combined with the prior's medicine results in a different medicine being produced.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623